REMARKS

In the Office Action, claims 235-244, 327, 340, 353 and 366 were rejected under 35 USC 112, first paragraph as lacking written description. Claims 298, 299, 301-309, 330, 343, 356 and 369 were rejected under 35 USC 112, first paragraph as lacking written description. Claims 300, 310-318, 331, 344, 357 and 370 were rejected under 35 USC 112, first paragraph as lacking written description. Claims 225-234, 265-274, 319-322, 326, 329, 332-335, 339, 342, 345-348, 352, 355, 358-361, 365, 368 and 371-372 were rejected under 35 USC 112, first paragraph as lacking enablement. Claims 298, 299, 301-309, 330, 343, 356 and 369 were rejected under 35 USC 112, second paragraph as indefinite. Claims 323, 324, 336, 337, 349, 350, 362, 363 and 373 were found allowable but for dependence on a rejected base claim. Claims 215-224, 255-264, 325, 328, 338, 341, 351, 354, 364 and 367 were allowed.

Claims 364-373 have been amended to correct a typographical error. Claim 235 has been amended to recite that a deletion mutant of the polypeptide of SEQ ID NO: 2 is used to alter the fatty acid profile of oil from a microbial cell culture. No new matter is added.

Written Description

MPEP 2163 (III)(A) sets forth the procedural standard for determining the adequacy of the description of a claimed invention during prosecution:

> A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

The written description standard simply requires that one of skill can recognize the identity of the claimed subject matter in the disclosure. No particular form of disclosure is required.

> [T]he language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. ... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter

> purportedly described. *Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316, 1328,1329 (Fed. Cir. 2002)*, internal citations omitted.

Functional language is permitted in the claims, and functional descriptions of genetic material can satisfy the written description requirement. *Id. at 1324.*

The rejection of Claims 235-244, 327, 340, 353 and 366 as lacking written description

Claims 235-244, 327, 340, 353 and 366 were rejected under 35 USC 112, first paragraph, as lacking written description. This rejection is traversed. The Office Action alleged that the lack of a representative species of a deletion mutant, and lack of any particular structure to function/activity relationship, resulted in failure to adequately describe the invention. Claim 235 has been amended to recite that a deletion mutant of the polypeptide of SEQ ID NO: 2 is used to alter the fatty acid profile of oil from a microbial cell culture.

Applicants do fully describe the primary structure of the Δ-6 desaturase protein and DNA, and demonstrate the function of the protein associated with that structure. The claims at issue recite the demonstrated function as a limitation. Furthermore, there is no requirement that any particular example of the claimed deletion mutant must be disclosed.

> The "written description" requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution. ... The chimeric genes here at issue are prepared from known DNA sequences of known function. The Board's requirement that these sequences must be analyzed and reported in the specification does not add descriptive substance. The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes.

Capon v. Esshar, 418 F.3d 1349, 1358, 76 USPQ (BNA) 1078, 1085 (Fed. Cir. 2005).

The Applicants have taught a DNA sequence, an encoded protein, and the function of that protein. Deletion mutants of these now-known sequences retaining the now-known function can be prepared, and recognized, by one of skill following the teachings of the application. Requiring Applicants to prepare multiple deletion mutants of the functional protein they have taught would not add descriptive substance. *Capon.* Additionally, requiring the inventors to prepare such mutants would discourage the inventors from disclosing their

invention until this additional work had been completed, "in contravention to the guiding principles underlying 112." Rohm and Haas Co. v. Crystal Chem. Co. 722 F.2d 1556, 220 USPQ 289 (Fed. Cir. 1983).

One of skill in the art can recognize a deletion mutant of the fully disclosed SEQ ID NO: 2. Applicants have fully taught this sequence and demonstrated its function. The process of making a deletion mutant is known in the art and is described in the specification. One following the teachings of the application and making deletion mutants of SEQ ID NO: 2 will necessarily make functional deletion mutants thereof.

The preponderance of evidence demonstrates that deletion mutants of SEQ ID NO: 2 are described as required by 35 USC 112, first paragraph. Withdrawal of the rejection is respectfully requested.

The rejections of Claims 298, 299, 301-309, 330, 343, 356 and 369

Claims 298, 299, 301-309, 330, 343, 356 and 369 were rejected under 35 USC 112, first paragraph as lacking written description. Claims 298, 299, 301-309, 330, 343, 356 and 369 were also rejected under 35 USC 112, second paragraph as indefinite. These rejections are traversed.

The Office Action alleged that hybridization conditions suitable for selectively screening a recombinant DNA library are not adequately described to reasonably convey to one of skill that the inventors had possession of the claimed invention at the time of filing.

Ipsis verba support is not required to utilize particular language in the claims. Example 1 demonstrates the preparation of multiple *M. alpina* cDNA libraries, including a "full-length" library having approximately 3 x 106 clones with an average insert size of 1.77 kb. Example 2 describes the obtaining of a partial cDNA clone, Ma524, having desaturase homology and states that "a full-length cDNA [corresponding to this clone] was isolated from the *M. alpina* full length library." See Page 47, line 23 et seq. One of skill recognizes that the partial cDNA clone described in Example 2 would have been used as a probe to screen the full-length cDNA library described in Example 1 to obtain the full-length desaturase sequence. Furthermore, the application describes elsewhere at multiple points the use of the disclosed sequences as probes

to obtain desaturase sequences from cDNA libraries. See, for example, page 5 lines 25-26, the paragraph bridging pages 17-18, and page 21 lines 7-13.

The Office Action also alleged that one of skill would not know what conditions the Applicants would have used for hybridization in the selective screening recited in claim 298, and thus this term was indefinite; however, one of skill need only be able to ascertain the conditions that meet the claim limitation for the claims to be sufficiently clear and definite.

Applicants are permitted to use relative standards, and have recited such a standard. One of skill could determine the full range of hybridization conditions which meet this claim limitation within at most two weeks. No evidence has been provided that one of skill could not determine such conditions. Ample evidence has been provided that one of skill can determine hybridization conditions given a known sequence and a library of defined source material. Claim 298 is limited to *Mortierella* as a library source, which genus contains a limited number of species. Claim 299 is further limited to *M. alpina*, which contains the actual source material used to obtain the disclosed sequences. One of skill can determine the range of conditions that meet the claim limitations, which recite clear standards.

As the disclosure permits one of skill to recognize the claimed invention, the written description requirement has been met for claims 298, 299, 301-309, 330, 343, 356 and 369. As the claim language permits one of skill to determine the metes and bounds of protection, claims 298, 299, 301-309, 330, 343, 356 and 369 meet the requirements of 35 USC 112, second paragraph. Withdrawal of these rejections is respectfully requested.

<u>The rejection of Claims 300, 310-318, 331, 344, 357 and 370 as lacking written description</u>

Claims 300, 310-318, 331, 344, 357 and 370 were rejected under 35 USC 112, first paragraph as lacking written description. This rejection is traversed.

As previously stated, claim 300 invokes 35 USC 112, sixth paragraph. Where a corresponding structure is disclosed in the specification for a functional claim limitation under 112(6), the written description requirement is satisfied. MPEP 2181. Here, the Office Action admits that a representative species from *M. alpina* is described. Office Action, page 3, third

full paragraph. The examples demonstrate the function for this sequence as recited in the claims, that of desaturating a fatty acid between carbons 6 and 7.

As the specification describes a structure having the function recited in the claim, the written description requirement is satisfied for claim 300 and claims ultimately dependent thereon. Withdrawal of this rejection is respectfully requested.

The rejection of Claims 225-234, 265-274, 319-322, 326, 329, 332-335, 339, 342, 345-348, 352, 355, 358-361, 365, 368 and 371-372 as lacking enablement

Claims 225-234, 265-274, 319-322, 326, 329, 332-335, 339, 342, 345-348, 352, 355, 358-361, 365, 368 and 371-372 were rejected under 35 USC 112, first paragraph as lacking enablement. This rejection is traversed.

The Office Action alleges that various grounds render the claims lacking in enablement, many of these allegations having no relation to the claim language (e.g, Δ12-desaturases). In light of *Ex parte Bandman*, claims relating to 95% homology are now found allowable. However, *Bandman* presented claims with no less than 95% homology, and no holding was provided as to the limits. The principles underlying the *Bandman* decision remain, that it is not enough to sustain a rejection to simply say too much experimentation would be required; evidence must be provided as to how much experimentation is required. The Office Action merely alleges the experimentation would be undue, without any evidentiary support.

The disclosure fully teaches the protein and DNA sequences of the *M. alpina* Δ6-desaturase, as well as methods of manipulating sequences, and of testing for protein function. One of skill in the art could make sequences having 60%, 80%, 90% (or 95%) homology to the disclosed sequences by following the teachings in the application and applying those teachings to the disclosed sequences with ordinary experimentation. One of skill could further make hybridizing sequences and deletion mutants based on the disclosed sequences which would retain functional activity. The Office Action admits that assays are disclosed for determining desaturase activity, and Applicants have provided evidence of record that one of skill can functionally screen a large number of mutants in a given amount of time.

In the art of manipulating a fully disclosed sequence having a fully disclosed function, it is predictable that mutations can be made that will still retain function of the protein. Such experimentation is routine in the art of manipulating disclosed sequences. It is routine to generate deletions and point mutations, which can have detectable homology, or whose coding sequences maintain ability to hybridize under conditions suitable for screening libraries. Furthermore, such claim scope is appropriate and is necessary to protect the inventors' contribution and avoid misappropriation of their invention by those who would seek to make minor alterations in the sequences they have taught.

The Office Action admits that the techniques for making mutations in a disclosed sequence are known in the art. The Office Action alleges that the amount of experimentation needed to redesign 10%, 20%, or 40% of the disclosed sequences is undue, but no factual evidence or findings have been provided as to how much experimentation would be needed. No evidence has been provided as to how much experimentation by one of skill would be needed to produce a homologous sequence (or a deletion mutant or a hybridizing sequence) meeting the claim limitations.

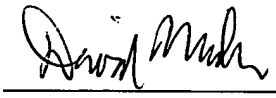
As the claims are presumed enabled until scientific evidence is provided sufficient to refute enablement, and no such evidence has been provided, lack of enablement has not been established. Caselaw establishes that rejections which merely assert the claims require undue experimentation without evidence do not satisfy the legal standard to establish lack of enablement. Accordingly, the claims stand enabled. Withdrawal of the rejections is respectfully requested.

CONCLUSION

Applicants request reconsideration of the claims in view of the above amendments and remarks. A notice of allowance is earnestly solicited. If a telephone conference would expedite allowance of this matter, the Examiner is welcome to contact the undersigned.

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 06-1135, billing reference no. 86014-8145.

Respectfully submitted,

By: 

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